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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,544	03/19/2002	Laurent Di Costanzo	C1190/20009	7903
3000 7590 11/05/2007 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOV, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			EXAMINER OH, SIMON J	
			ART UNIT 1618	PAPER NUMBER
			NOTIFICATION DATE 11/05/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No. 09/914,544	Applicant(s) COSTANZO ET AL.	
	Examiner Simon J. Oh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, and petition for extension of time, all received on 10 August 2007. Receipt is acknowledged of the executed declaration under 37 C.F.R. 1.132, received on 28 August 2007.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 21-39 under 35 U.S.C. 103(a) as being unpatentable over Hunter *et al.* in view of Schmitz *et al.* and Valentine is maintained.

The rejection of Claims 40 and 41 under 35 U.S.C. 103(a) as being unpatentable over Hunter *et al.* in view of Schmitz *et al.* and Valentine is maintained.

Claims 31 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter *et al.* (U.S. Patent No. 6,391,337) in view of Schmitz *et al.* (U.S. Patent No. 6,079,968)

The Hunter *et al.* patent teaches pharmaceutical dosage forms for a rapidly disintegrating tablet (See Column 5, Lines 27-45; Example 8; and Figure 3). Processes for making this tablet are disclosed (See Column 2, Line 52 to Column 3, Line 55). The tablets can carious comprise saccharides as inert fillers, including sucrose, dextrose, lactose, xylitol, fructose, and sorbitol (See Column 12, Lines 1-13). A lubricant, such as

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magnesium stearate, can be included in the tablets in amounts ranging from 0.01% to 4.0% by weight of the dosage form (See Column 10, Lines 1-23). A disintegrant may be included as well, such as sodium starch glycolate and cross-linked polyvinyl pyrrolidones (See Column 11, Lines 52-67). Other additives may also be included as well, such as flavorants, sweeteners, and coloring agents (See Column 15, Lines 41-53). The dosage forms are prepared by direct compression of a dry granulate (See Claim 1).

The Hunter *et al.* patent does not explicitly teach methods of manufacturing tablets wherein the lubricant is entirely or mostly applied to the outer surface of the tablet.

The Schmitz *et al.* patent discloses a device that sprays powdered lubricants onto punches and dies of a tablet press. Such a device can be readily retrofitted into existing machinery and provide an improved method of tablet manufacture (See Column 1, Line 35 to Column 3, Line 36).

It would be obvious to one of ordinary skill in the art to combine the teachings of the Hunter *et al.* and Schmitz *et al.* into the objects of the instantly claimed invention. One of ordinary skill in the art would be motivated to combine the Hunter *et al.* and Schmitz *et al.* references to create an improved process of making pharmaceutical dosage forms that meters out tablet lubricants in a more efficient manner in such a way that minimizes caking of lubricants onto tablet dies. As is been disclosed that the device disclosed in Schmitz *et al.* can be readily retrofitted into existing machinery, it is the position of the examiner that the two references can be combined by one of ordinary skill in the art with a reasonable expectation of success.

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Furthermore, the Hunter *et al.* patent describes previous difficulties in the prior art with the formulation of lubricants in tablets, where the prolonged blending of a lubricant in a granulated tablet mixture results in a tablet with decreased tablet hardness and strength when the mixture is compressed into a tablet (See Column 2, Lines 29-55). It is clear then to one of ordinary skill in the art that the modification presented by the Schmitz *et al.* patent would present a viable alternative to solving that particular problem, so as to result in a tablet where its hardness and strength have not been compromised.

Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed on 10 August 2007 have been considered but are not considered persuasive.

Much of the applicant's arguments are directed toward the disclosure in the Hunter *et al.* reference where the tablets disclosed therein are alleged as being directed to a coated tablet composition. While this may be true for the invention described in the claims of that patent, the invention described throughout the reference are not solely directed toward that embodiment. For instance, the examples described therein clearly show tablets that do not have a coating. The coating applied to the disclosed tablets is also clearly described as being optional (See Column 14, Lines 62-65). In a proper analysis of the prior art, alternative embodiments should not be ignored in favor of only preferred embodiments, since prior art references are valid for all that they contain. See MPEP § 2111 and 2123.

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The applicant also argues that there should be an incentive to combine the cited references. However, the decision in *KSR International Co. v. Teleflex Inc.* forecloses that argument, where a specific teaching, suggestion or motivation is required to support a finding of obviousness. The Hunter *et al.* reference deals with issues that are similar to those addressed by the applicant, where the prolonged blending of a lubricant in a granulated tablet mixture results in a tablet with decreased tablet hardness and strength when the mixture is compressed into a tablet (See Column 2, Lines 29-55). As it has been established that the prior art is not strictly limited to only those tablets that are coated, there is an ongoing concern about uncoated compressed tablets containing a lubricant having sufficient tablet strength. As it has been established above, the Schmitz *et al.* patent provides an alternate means of addressing that issue, where the lubricant may be located on the exterior of the tablet, rather than being present in a homogeneous distribution throughout the tablet.

The declaration under 37 CFR 1.132 filed 28 August 2007 is insufficient to overcome the rejection of Claims 21-42 based upon obviousness as set forth in the last Office action because it does not properly rebut the issue of what was considered to be an unexpected result in the prior art at the time the instant application was filed. The prior art discloses tablets with similar properties of hardness and tablet disintegration time (See Hunter *et al.*, Example 8; and Figures 2 and 3). Therefore, it would appear that the properties of the instantly claimed invention are not clearly unexpected over what was known in the prior art.

Furthermore, as stated above, it is the position of the examiner that one of ordinary skill in the art would readily recognize the value of modifying the process

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disclosed in Hunter *et al.* in view of the Schmitz *et al.* patent, as the problems presented by blending a lubricant into a granulated dry tablet mixture is resolved by removing the lubricant from the tablet mixture and applying it onto the tablet press itself during the actual tablet compressing process. Therefore, the claims remain rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sj0


MICHAEL G. HARTLEY
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